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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,436	08/22/2008	Sylvie Pridmore-Merten	3712036.00745	1948

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EXAMINER	
HOBBS, LISA JOE	
ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
06/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,436	PRIDMORE-MERTEN, SYLVIE	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16,18-21,31-33,35-37,39 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16,18-21,31-33,35-37,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Status

Claims 1-8, 12-16, 18-21, 31-33, 35-37, 39-40 are active in the case. Claims 1-8, 12-16, 18-21, 31-33, 35-37, 39-40 are under examination; no claims are withdrawn as drawn to a non-elected invention. Claims 9-11, 22-30, 34 and 38 have been cancelled by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 12-16, 18-21, 31-33, 35-37, 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Simone (US 6,380,252 A), Cavazza (US 6,063,820 A and 6,348,495 A), Hamilton (US 2002/ 077349 A and 2003/060503 A), Germano (US 6,503,506 A), and Kosbab (US 2001/0031744 A1), in vew of Murad (US 20030224071 A1), .

De Simone teaches "[a] method is provided for increasing the levels of IGF-1 for the therapeutic treatment or prophylaxis of cytological disorders or diseases related to IGF-1 selected from the group including neuropathies of the optic nerve and of the olfactory nerve, neuralgia of the trigmeninal nerve, Bell's paralysis, amyotrophic lateral sclerosis, osteoporosis, anthropathy, arthritis, cervical spondylosis and hernia of the intervertebral discs clinical syndromes of reduced height, cachexia and acute or chronic hepatic necrosis, Turner's syndrome, sarcopoenia, growth hormone insensitivity syndromes, obesity, asthenia, myasthenia and heart asthenia, immunodeficiences and reperfusion injuries, and for the cicatrization of wounds, the healing of ulcers, the treatment of burns, tissue regeneration, cutaneous, intestinal and hepatic tissue regeneration and the formation of dentine, that includes administering, to a patient in need thereof, at least one selected from the group including L-acetylcarnitine, L-isovalerylcarnitine, and L-propionylcarnitine or pharmacologically acceptable salts thereof. The present invention also relates to a method and composition for treating HCV and/or increasing the levels of IGF-1 of a patient in need thereof, the composition including at least one selected from the group including L-acetylcarnitine, L-isovalerylcarnitine, L-propionylcarnitine and pharmacologically acceptable salts thereof and mixtures thereof; and at least one selected from the group including L -carnitine, coenzyme Q10, vitamin E and Se-L-methionine and pharmaceutically acceptable salts and derivatives thereof and mixtures thereof" (abstract).

Cavazza ('495) teaches "[a] medical food for diabetics is disclosed which comprises as characterizing active ingredients .gamma.-linolenic acid and at least one alkanoyl-L -carnitine, e.g. acetyl-L -carnitine and/or propionyl-L –carnitine" (abstract) and that "[a]n object of the present invention is to provide a medical food for diabetics which enables them to compensate

for the reduced metabolism of essential fatty acids typical of such subjects. In particular, the object of the present invention is to provide a medical food of this type which makes it possible to by-pass the enzyme blockade caused by the reduced activity of omega-6-desaturase which occurs in diabetics and gives rise to inadequate conversion of linoleic acid into y-linolenic acid and thus to a reduced production of prostaglandin and leukotriene precursors (BSUM paragraph 17). Also taught (Cavazza '820) is "a new therapeutic use of the lower alkanoyl L-carnitines and their pharmacologically acceptable salts to produce pharmaceutical compositions for the treatment of chronic intestinal disorders, in particular inflammatory bowel diseases, more particularly, ulcerative colitis or celiac disease" (BSUM paragraph 1).

Cavazza ('495) teaches at Example 2: "S.C., male, 20 years old, height 178 cm, weight 69 Kg. Regularly born, he was breast-fed by her mother for about 40 days. At about 9 months diarrhoea and meteorism appeared, lasting one month. Regular growth and sexual development. Measles. In 1995 a blister dermatitis appeared, with strong itching. After different hypotheses, a Duhring dermatitis was diagnosed. An EGDS was carried out with biopsies reporting celiac disease. A rigid gluten-free diet started. Dermatitis was resolved, but still 2-3 daily discharges, with poorly formed faeces and abdominal pains were reported. The patient started the treatment with propionyl L -carnitine (2 grams/day orally for two months), with an improvement of the general symptomatology. After 4 months the patient started sporting activity again".

Hamilton (2002) teaches "methods to treat age-related vision losses. The method comprises administering a combination of a carnitine and an oxidant. Preferably the oxidant is thioctic acid. Preferably 0.12 grams to 3 grams of carnitine (particularly ALC) and 0.12 and 1.5 grams of R-.alpha.-lipoic acid are administered. Optionally, coenzyme Q and/or creatine also are

administered. Preferably 10 mg to 500 mg/day of coenzyme Q10 and 1 to 30 grams/day of creatine are administered" (abstract). As well, Hamilton also teaches (2003) "compositions to meet the needs of aged pets and other animals. A pet food formulated for senior pets provides .alpha.-lipoic acid at about 0.15 to 50 mg/kg body weight/day, carnitine at about 0.5 to 100 mg/kg/day, and optionally coenzyme Q at about 0.01 mg/kg/day and/or creatine at about 15 mg to about 1 g/kg/day. A pet treat for senior pets provides .alpha.-lipoic acid at about 0.15 to 50 mg/kg body weight/day, carnitine at about 0.5 to 100 mg/kg/day, and optionally coenzyme Q at about 0.01 mg/kg/day and/or creatine at about 15 mg to about 1 g/kg/day. A pet supplement for mature pets offers .alpha.-lipoic acid at about 0.15 to 50 mg/kg body weight/day, carnitine at about 0.5 to 100 mg/kg/day, and optionally coenzyme Q at about 0.01 mg/kg/day and/or creatine at about 15 mg to about 1 g/kg/day" (abstract).

Germano teaches "[a] nutritional supplement...for treating chronic debilitating diseases such as HIV/AIDS to overcome conditions of oxidative stress, decreased lean muscle mass, decreased energy production (mitochondrial failure) and support immune function. It comprises orally administrable superoxide dismutase (SOD), preferably SOD/GLIADIN, in combination with other antioxidant/immune support components (Beta Glucans, Nucleotides, Fruit Polyphenols); High Immunoglobin Whey; (undenatured whey), Ornithine alpha ketoglutarate (OKG), Branched Chain Amino Acids and Glutamine to reduce loss of lean muscle mass; and Coenzyme Q 10, D-Ribose and L-Carnitine to provide energy support (decrease mitochondrial failure).

Kosbab teaches "nutrient and therapeutic compositions for treatment and prevention of symptoms and disease conditions associated with microangiopathy and macroangiopathy and to

methods using the compositions. In particular, the invention relates to compositions useful in the treatment of diabetic retinopathy and nephropathy, to compositions useful in the treatment of other retinal disorders including macular degeneration and cataracts, to compositions useful in wound healing, to compositions useful for treatment and prevention of neuropathy, to compositions useful for treatment and prevention of cardiovascular disease and to compositions useful for the treatment and prevention of dental and periodontal disorders" and that "[v]ascular degeneration is directly associated with cardiovascular disease, atherosclerosis and plaque deposition and indirectly associated with degenerative conditions of the retina (including retinopathy), kidney (nephropathy) and nervous system (neuropathy), as well as skin ulcers" [0003].

He also teaches that "L -Carnitine is an essential co-factor of fatty acid metabolism. Significantly decreased plasma carnitine levels are common in insulin dependent diabetics including those with nephropathies. This implies that such patients may suffer from inadequate ATP reserves that could cause fatigue and oxidative stress due to reduced lipid metabolism caused by faulty transport of fatty acids across mitochondrial membranes. Carnitine supplementation supports increases in fat utilization and oxygen uptake while decreasing plasma lactate levels and respiratory quotients. Carnitine has been shown to reduce ketones, LDL and triglycerides and increase HDL while acting as a vasodilator. Low carnitine levels may correlate with low plasma albumin and edema. L -Carnitine can be provided as N-acetyl-l -carnitine hydrochloride, the preferred form for this invention. Carnitine can be also be provided as the 1- or d,1-form as hydrochloride or other salts" [0453].

Murad et al. teach an "invention [that] relates to compositions and methods for managing connective tissue disorders in a patient, a sugar compound that is converted to a glycosaminoglycan, a primary antioxidant component, at least one amino acid component, at least one transition metal component, at least one moisturizing agent, at least one fatty acid" [abstract}], primarily via topical administration, but also that "[o]ther moisturizing agents that hydrate the skin and connective tissue and are useful in the compositions and methods of the present invention include, but are not limited to, panthenol; primrose oil; GLA 3 and other fish oils that may include, for example, the omega-3 and omega-6 oils; and flax seed oil. Preferably, these moisturizing agents are administered orally" [0056, claim 3]. They teach that various components, including vitamins and grape seed oil, are beneficial for the skin of a patient suffering from various skin ailments, and that vitamin ingestion should be monitored when being administered orally to be sure that over dosage does not occur [0067].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of De Simone, Cavazza, Hamilton, Germano and Kosbab to achieve the invention as recited. One would be motivated to do so in order to develop non-invasive treatments, especially treatments that would be part of a daily schedule such as food, for various medical problems as outlined in the prior art. One would have a reasonable expectation of success since the medically oriented foodstuffs and compositions taught also comprise the natural compounds, such as isoprenoids, terpenes, ginkgo biloba, etc., disclosed in the instant claims.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicants argue that each of the references does not teach the invention as currently recited in the claims. However, when taken as a whole, the references clearly teach the medicinal use of L-carnitine when administered in conjunction with anti-oxidants and other medicinal and nutriceutical elements in the ranges recited in the claims. Applicants particularly argue that the prior art does not teach the administration of the compounds as recited in the claims, that the prior art references teach completely unrelated products having completely unrelated objectives. However, it is noted that the objectives of the administration of the compounds is presented in the preambles to the instant claims, which are given limited weight and consideration when determining patentability. However, it is noted that Kosbab specifically states that L-carnitine administered to a subject may assist with lipid metabolism and that skin disorders are contemplated as within the metes and bounds of his treatment methods.

The actual method step, administration of L-carnitine and anti-oxidant compositions to animals or humans in need thereof is clearly taught in the cited prior art at the levels recited in the claims. The final beneficial effect of the compositions would be expected to be the same whether administered in response to a skin condition or a vision condition or a nutrient uptake condition. Kosbab does specifically state that L-carnitine may assist a subject with lipid metabolism problems.

Applicants state that the prior art does not teach a combination of L – carnitine with Vitamins C and E, and grape seed extract at the levels recited in the claims, however the prior art teaches the recited components at many dosage amounts, comprising and encompassing the large

dosage range recited by applicants. Applicants argue that the prior art recited would not be applied to the instant diseases, however the prior art clearly teaches that administration of L-carnitine and antioxidants such as Vitamin C are well known to stimulate lipid metabolism and this is known be beneficial to skin (Hamilton et al., p. 1). Applicants argue that one of skill wouldn't use references that are directed at amelioration of other medical conditions, however the skilled artisan is aware that such compositions and administration of them is beneficial to the patient's lipid metabolism pathways and the final medical application is not as pertinent as the fact that L-carnitine and antioxidants, such as Vitamin C, are known to affect lipid metabolism in a positive manner. Indeed, applicant supports this by having groups of claims to medicaments and dietary supplements for human application and animal application, as well as methods of administration, all relating to changing lipid metabolism, as is taught in the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Hotelling - Generally, 9-6 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh